Journal of Adolescent Health 54 (2014) S21–S23

ELSEVIER

JOURNAL OF ADOLESCENT HEALTH

www.jahonline.org

Commentary

Office of Adolescent Health Medical Accuracy Review Process—Helping Ensure the Medical Accuracy of Teen Pregnancy Prevention Program Materials

Jo Anne G. Jensen, Ph.D. [a,*], Elizabeth L. Moreno, M.A., C.H.E.S. [b], and Tara M. Rice, M.D., M.P.P. [a]

[a] Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health, Office of Adolescent Health, Rockville, Maryland
[b] Planning and Learning Technologies, Inc. (Paltech), Arlington, Virginia

Keywords: Teen pregnancy; Evidence-based programs; Medical accuracy review; STI prevention; Pregnancy prevention; Curricula review; Birth control

A B S T R A C T

The Office of Adolescent Health (OAH) developed a systematic approach to review for medical accuracy the educational materials proposed for use in Teen Pregnancy Prevention (TPP) programs. This process is also used by the Administration on Children, Youth, and Families (ACYF) for review of materials used in the Personal Responsibility Education Innovative Strategies (PREIS) Program. This article describes the review process, explaining the methodology, the team implementing the reviews, and the process for distributing review findings and implementing changes. Provided also is the definition of "medically accurate and complete" as used in the programs, and a description of what constitutes "complete" information when discussing sexually transmitted infections and birth control methods. The article is of interest to program providers, curriculum developers and purveyors, and those who are interested in providing medically accurate and complete information to adolescents.

In 2010, competitive grants to public and private entities were made available to fund programs to reduce (1) teen pregnancy; (2) behavioral risk factors underlying teenage pregnancy; and (3) other associated risk factors. The Office of Adolescent Health (OAH) was charged with administering the Teen Pregnancy Prevention (TPP) Program grants, and the Administration on Children, Youth, and Families (ACYF) was charged with administering the Personal Responsibility Education Innovative Strategies (PREIS) Program grants. These grant programs administered by OAH and ACYF are required to provide information that is medically accurate and complete. OAH's mandate for medical accuracy is based on statutory language contained in the Fiscal Year 2010 appropriations bill [1], which first authorized the TPP program, as well as annual appropriations bills thereafter. ACYF is also required to provide medically accurate and complete information as directed in the Patient Protection and Affordable Care Act (P.L.111-148) [2]. The funding announcements [3,4] for TPP and PREIS grantees stated that all core curricula materials (e.g., facilitator manuals, student handbooks, videos, posters) proposed for use in TPP- and PREIS-funded projects must be reviewed for medical accuracy before program implementation. The definition of medical accuracy used by OAH and ACYF was adopted from the Patient Protection and Affordable Care Act and reads as follows:

> The term "medically accurate and complete" means verified or supported by the weight of research conducted in compliance with accepted scientific methods; and published in peer-reviewed journals, where applicable or comprising information that leading professional organizations and agencies with relevant expertise in the field recognize as accurate, objective, and complete [2].

Conflicts of Interest: The authors declare no conflicts of interest.

Disclaimer: Publication of this article was supported by the Office of Adolescent Health, U.S. Department of Health and Human Services. The opinions or views expressed in this paper are those of the authors and do not necessarily represent the official position of the Office of Adolescent Health, U.S. Department of Health and Human Services.

* Address correspondence to: Jo Anne G. Jensen, Ph.D., HHS—Office of Adolescent Health, 1101 Wootton Parkway, Suite 700, Rockville, MD 20852.
E-mail address: JoAnne.Jensen@hhs.gov (J.G. Jensen).

1054-139X matter Published by Elsevier Inc. on behalf of Society for Adolescent Health and Medicine. Open access under CC BY-NC-ND license.
http://dx.doi.org/10.1016/j.jadohealth.2013.11.022

Before a grant application was submitted, applicants needed to determine whether they wanted to (1) select a program from the Health and Human Services (HHS) Pregnancy Prevention Research Evidence Review List of Evidence-Based Programs (EBP) [5] for replication; (2) propose a significant adaptation of an EBP program model from the EBP list; or (3) propose to test a new and innovative approach. After funding was awarded through the competitive process, OAH TPP and ACYF PREIS grantees submitted their curricula and other core educational materials to the medical accuracy review team to ensure medical accuracy and completeness. Compliance with this review process was a condition attached to the notice of grant award.

Review Process

The medical accuracy review is carried out by a contractor, Planning and Learning Technologies Inc. (Paltech), who obtained the contract through a competitive award process in 2010. Grantees, TPP and PREIS, do not receive HHS approval to implement their programs until the medical accuracy review is complete, and any necessary changes are addressed and incorporated into their programs. The contractor assembled a network of multidisciplinary professional experts on adolescent health, reproductive health, pediatrics, and other disciplines that focus on teenage pregnancy prevention and other relevant topics. The contractor provides training for the medical experts so that reviewers become familiar with a standardized review form and a list of recommended resources and references to assist with verifying information and substantiating recommended changes. The review form provides a systematic way to review materials, explain issues found, and recommend ways to address identified problems.

The medical accuracy review provides a rigorous review of materials used in TPP and PREIS programs. It is important for materials used in the programs covering medical topics (e.g., sexually transmitted infections [STIs], human immunodeficiency virus/acquired immunodeficiency syndrome [HIV/AIDS], and contraception) to contain accurate, up-to-date, and complete information. References for standards of care include the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, *Contraceptive Technology*, 20th revised edition, and peer-reviewed, published journals of health and science.

The materials that require review are all core curricula and related educational materials for use in TPP and PREIS projects. These include, but are not limited to, teacher manuals, videos, podcasts, scripts, student booklets, pamphlets, and handouts. Materials used for a control group in an evaluation must also be reviewed for medical accuracy.

Materials are sent to the medical accuracy review contractor. All curricula materials submitted for review undergo two independent reviews, and in select cases, three, to ensure inter-rater reliability. The reviewers examine the materials for medical information and create a report, using the standardized review form. All materials are evaluated to determine whether they contain information that is medically inaccurate or incomplete.

For each medical accuracy issue noted, the report will include the location in the curriculum/educational material (e.g., page number, line or paragraph number), the medical topic addressed, a description of the medical accuracy issue, recommendations for correcting the issue, and substantiating references. Once the reviewers have assessed a particular curriculum or educational material, the reports are sent to the medical accuracy review contractor, who reviews and synthesizes the reports into one consolidated report. After the consolidated report is finalized, it is sent (accompanied by the individual reviewer reports) to OAH or ACYF, as appropriate for review. If there are questions or concerns from either OAH or ACYF, the medical accuracy review contractor contacts the reviewers for discussion. Once any questions or concerns are resolved, the final report is sent to the grantee.

Two letters accompany the final report. One letter describes the review process and the other discusses possible copyright implications. Grantees are not expected to alter materials beyond correcting the medically inaccurate information, and grantees are encouraged to contact the copyright holder for written permission before making any alterations to curriculum materials. The grantee is asked to confirm receipt of the medical accuracy report and both letters.

If materials need modifications, grantees are required to submit to their respective OAH or ACYF project officer plans for addressing the results of the medical accuracy review within 30 days of receiving the report. The project officer reviews the changes and notifies each grantee if the changes are acceptable. The medical accuracy contractor is also available to help with recommended modifications if there are any issues.

A courtesy copy of the final report is shared with the developer or purveyor of the curriculum materials, along with a letter describing the review process. The letter also explains that although the medical accuracy review report details the medical accuracy issues found during the review, any revised curricula developed in response to the report should neither be characterized as approved by OAH/ACYF nor contain any language indicating that all medical accuracy recommendations have been incorporated into the curriculum. The Department of Health and Human Services policy prohibits HHS from giving preferential treatment to any non-Federal entity; therefore, entities may not include statements in their materials that may be perceived to be endorsements by HHS.

The Review

To date, more than 70 curricula, ranging in size from 30 to more than 1,000 pages, have been reviewed. In addition, multiple supplemental items such as brochures, PowerPoint presentations, handouts, videos, and flipcharts have been reviewed.

Examples of some medical accuracy issues identified include the need to add information about new contraceptives as they are approved by the U.S. Food and Drug Administration, and new vaccine schedules for immunizations. In some instances, medical accuracy issues stem from incomplete language that simply needs updating. For example, when discussing the role of condoms in STI and HIV prevention, risk reduction language should be used, along with the specification that latex condoms or polyurethane (if allergic to latex) decrease the risk of STI/HIV transmission. In addition, it is necessary to point out that the level of risk reduction when using a condom varies with the different types of STIs [6]. Language needs to emphasize that if engaging in sexual activity, the most effective way to reduce the risk of becoming pregnant and/or getting an STI is to use a latex (or polyurethane) condom plus an additional method of birth control [7–9]. It is important to include information on abstinence; to define abstinence as abstaining from oral, anal, and

vaginal sex; and to discuss sexual abstinence as the most reliable way to prevent pregnancy and STI/HIV infection [10].

Sexually Transmitted Infections

When OAH/PREIS grantees provide information about STIs, they need to address the following infections and diseases to be considered "complete": syphilis, gonorrhea, chlamydia, herpes simplex II, hepatitis B, human papillomavirus, trichomoniasis, and HIV/AIDS (i.e., Centers for Disease Control and Prevention STD Fact Sheets [11–13]). The information needs to include the (1) type of organism that causes the STI (virus/bacteria/parasite); (2) modes of transmission; (3) symptoms; (4) treatment; (5) possible complications/sequelae; and (6) prevention details. If an immunization exists for a given STI, such as human papillomavirus and hepatitis B, this information should also be included. In addition, a recommendation of HIV and STI testing for sexually active individuals is extremely important.

Birth Control Information

Birth control information needs to describe each method, including (1) how the method works; (2) duration of contraceptive effects; (3) effectiveness/failure rates (typical/perfect use); (4) whether it provides no protection or reduces the risk of HIV/AIDS and other STIs; (5) health risks/drawbacks (medical/personal); and (6) benefits (medical/personal) associated with the method.

Closing Remarks

Medical information is dynamic and evolving as research is conducted, and new knowledge is learned. Information from 10 years ago may have advanced or even been refuted. At times, inaccurate medical information is given the appearance of truth and authority by frequent and popular repetition. For these reasons and more, it is imperative that health information being provided for TPP and PREIS program participants be reviewed, updated, and corrected when necessary. The Office of Adolescent Health and ACYF use a review process for grantee program materials that identifies issues, addresses inaccuracies, and provides updated and accurate information. This process allows grantees to benefit from the expertise of medical reviewers; the system put in place informs grantees about medical issues found in their program materials, as well as provides recommendations for responding to those issues so that they are compliant with the medical accuracy requirement as prescribed by Congress.

Funding Sources

The medical accuracy review project is funded by Contract number HHSP23320095648WC, from the Office of Adolescent Health to Planning and Learning Technologies, Inc. and from partial funding support from the Administration of Children, Youth and Families. The medical accuracy review project was managed with staff support by the Office of Adolescent Health, U.S. Department of Health and Human Services.

References

[1] U.S. Government Printing Office. PUBLIC LAW 111 -117 –DEC. 16, 2009. Consolidated Appropriations Act, 2010. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-111publ117/pdf/PLAW-111publ117.pdf. Accessed December 30, 2013.
[2] U.S. Government Printing Office. PUBLIC LAW 111 -148 –MAR. 23, 2010. Patient Protection and Affordable Care Act. Available at: http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf. Accessed December 30, 2013.
[3] Department of Health and Human Services, Office of Adolescent Health. Teenage Pregnancy Prevention (TPP): Research and Demonstration Programs and Personal Responsibility Education Program (PREP) Funding Opportunity Announcement and Application Instructions (2010). Available at: http://www.hhs.gov/ash/oah/grants/assets/foa_tpp_tier_2.pdf. Accessed December 30, 2013.
[4] Department of Health and Human Services, Office of Adolescent Health. Teenage Pregnancy Prevention: Replication of Evidence-based Programs Funding Opportunity Announcement and Application Instructions (2010). Available at: http://www.hhs.gov/ash/oah/news/assets/tpp_funding_announcement_ebp.pdf. Accessed December 30, 2013.
[5] Department of Health and Human Services, Office of Adolescent Health. TPP Resource Center: Evidence-Based Programs. Available at: http://www.hhs.gov/ash/oah/oah-initiatives/teen_pregnancy/db/programs.html. Accessed December 30, 2013.
[6] Department of Health and Human Services, Centers for Disease Control and Prevention. Condoms and STDs: Fact Sheet for Public Health Personnel. Available at: http://www.cdc.gov/CONDOMEFFECTIVENESS/docs/Condoms_and_STDS.pdf. Accessed December 30, 2013.
[7] Hatcher RA, Trussell J, Nelson AL, et al. Contraceptive Technology. Twentieth Revised Edition. Atlanta, GA: Ardent Media, Inc.; 2011.
[8] Committee on Adolescence. Condom use by adolescents. Pediatrics 2013; 132:973-81. Available at: http://pediatrics.aappublications.org/content/early/2013/10/23/peds.2013-2821.full.pdf. Accessed December 30, 2013.
[9] Healthy People 2020. Available at: http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicid=13. Accessed December 31, 2013.
[10] Department of Health and Human Services, Centers for Disease Control and Prevention. Sexually Transmitted Diseases: Prevention. Available at: http://www.cdc.gov/std/prevention/default.htm. Accessed December 30, 2013.
[11] Department of Health and Human Services, Centers for Disease Control and Prevention. Sexually Transmitted Diseases: CDC Fact Sheets. Available at: http://www.cdc.gov/std/HealthComm/fact_sheets.htm. Accessed December 30, 2013.
[12] Department of Health and Human Services, Centers for Disease Control and Prevention. Hepatitis B Information for the Public. Available at: http://www.cdc.gov/hepatitis/B/PatientEduB.htm. Accessed December 30, 2013.
[13] Department of Health and Human Services, Centers for Disease Control and Prevention. HIV/AIDS: Fact Sheets. Available at: http://www.cdc.gov/hiv/library/factsheets/index.html. Accessed December 30, 2013.